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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/615,361 | 07/08/2003 | Charles N. Serhan | 14021.03 | 8819 |

7590 06/09/2005

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| EXAMINER | |
|---|---|
| DELACROIX MUIRHEI, CYBILLE | |
| ART UNIT | PAPER NUMBER |
| 1614 | |

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/615,361 | SERHAN ET AL. | |
| | Examiner | Art Unit | |
| | Cybille Delacroix-Muirheid | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *5-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Detailed Action***

1. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serhan 6,653,493.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Response to Amendment(s)***

The following is responsive to applicant's amendment received Sep. 30, 2004.

Claims 9-18 are cancelled. No new claims are added. Claims 5-8 are currently pending.

Applicant's arguments traversing the previous rejection of claims 5-8 under 35 USC 103(a), set forth in paragraph 1 of the office action mailed July 1, 2004, have been carefully considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed July 1, 2004 with the following additional comment:

Applicant argues it is well settled that there must be some motivation, teaching or suggestion of the desirability of the invention. Furthermore, the use of hindsight in determining obviousness is improper and the examiner cannot use the invention as a "blueprint" for identifying a suggestion or motivation. Therefore, applicant asserts that Serhan does not teach or suggest or provide any motivation or expectation of success to treat restenosis in a tissue wherein smooth muscle cell migration occurs "following angioplasty" with a lipoxin $A_4$ compound. The examiner has not identified in Serhan a

motivation, suggestion or teaching for selecting elements of the reference to render obvious the claimed methods.

Said arguments have been considered but are not found to be persuasive.

The Examiner respectfully maintains that Serhan renders obvious the claimed methods. First of all, the examiner agrees with applicant that obviousness analysis require some motivation, suggestion or teaching, in the prior art, of the desirability of the invention. However, the CAFC has held "a finding of obviousness does not require existence of express, written motivation to combine in prior art, since motivation to combine may be found in the nature of the problem to be solved." Please see Ruiz v. A.B. Chance Co., 69 USPQ2d 1686, 1690 (CAFC 2004). In this case, there is no written express motivation to render obvious the claimed methods. Yet, the examiner respectfully submits that motivation is to be found in the nature of the problem to be solved.

Serhan's solution to the problem of undesired, abnormal cell proliferation is to treat a patient in need thereof with an effective amount of a lipoxin-A4 compound ($LXA_4$ or 15-epi-lipoxin-$A_4$ derivatives). Serhan specifically teaches that target cells to be treated can be undergoing abnormal cell proliferation in response to a stimulus such as restenosis (please see col. 35, lines 10-12). Therefore, one of ordinary skill in the art can reasonably conclude that the nature of the problem to be solved is treatment of restenosis, which occurs following "a stimulus." Serhan does not specifically teach that the stimulus is angioplasty, as claimed. However, the examiner respectfully submits that, absent evidence to the contrary, the fact that restenosis follows angioplasty or

some other type of stimulus does not render the claimed methods unobvious since the problem to be solved is the occurrence of restenosis. Therefore, since Serhan discloses that restenosis may be treated by administration of Lipoxin-A4 compounds, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Serhan to include patients suffering from or susceptible to restenosis following angioplasty (the problem) because one of ordinary skill in the art would reasonably expect the anti-proliferative property of the lipoxin-A4 compounds (the solution) to reduce or inhibit the occurrence of restenosis following angioplasty.

Finally, contrary to applicant's argument, the examiner maintains it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat patients suffering from restenosis following angioplasty because Serhan clearly suggests that restenosis, another type of abnormal cell proliferative disorder can be treated by the lipoxin-A4 compounds.

It is for these reasons the rejection is maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
May 27, 2005

REBECCA COOK
PRIMARY EXAMINER
GROUP 1200 /614